

Information Disclosure Statement ("IDS"), Mantooth is admitted prior art and cannot be sworn behind. For the reasons set forth below, the Examiner's conclusion is legal error.

Effective February 27, 1983, the U.S. Patent and Trademark Office amended Rule 97 to change the designation of information submitted by the Applicant pursuant to Rule 56 from "prior art statement" to "information disclosure statement." See 48 Federal Register 2696 (relevant section included). The change was made because "[i]nformation which is required to be submitted pursuant to § 1.56 may ultimately be determined not to be 'prior art'". Therefore, the PTO's policy is that information submitted in an IDS is not admitted to be prior art and that such information "may ultimately be determined not to be prior art."

The Federal Circuit has stated that "mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art." See *Abbott Laboratories, Inc v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003)(copy enclosed). The Federal Circuit further stated that:


According to Patent Office rules, "the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to the patentability defined in § 1.56(h)." 37 C.F.R. § 1.97(h) (2000). While valid prior art may be created by the admissions of a party, these admissions are generally characterized by statements made during prosecution describing certain work as "prior art." See *In re Nomiya*, 509 F.2d 566, 571 n.5 (CCPA 1975); *In re Fout*, 675 F.2d 297, 300-01 (CCPA 1982). Under certain circumstances, even an express representation that a reference cited in an IDS is prior art to pending claims is not sufficient to create prior art by admission. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346 (Fed. Cir. 2003). ***Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be material to prosecution of the pending claims.*** 37 C.F.R. § 1.56(a) (2000); see *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392 (Fed. Cir. 1986).

See *Abbott Labs* at 1279.

Based upon the forgoing, it is respectfully submitted that the Examiner's conclusion that information submitted in an IDS is an admission that the information is prior art is incorrect. This is confirmed by the PTO's comment when it implemented amended Rule 97 and by Federal Circuit case law.

Based on the foregoing, Applicant submits that his declaration swearing behind Mantooth removes Mantooth as prior art and, therefore, respectfully requests the allowance of claims 1-13. If for any reason the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, the Examiner is requested to contact the undersigned attorney for the purpose of arranging such an interview.

Respectfully submitted,



Nelson D. Nolte, Reg. No. 42,938
Polster, Lieder, Woodruff & Lucchesi, LC
12412 Powerscourt Dr. Ste. 200
St. Louis, Missouri 63131
Tel: (314) 238-2400
Fax: (314) 238-2401

48 FR 2696

29. Section 1.67 is revised to read as follows:

§ 1.67 Supplemental oath or declaration.

(a) A supplemental oath or declaration meeting the requirements of § 1.63 may be required to be filed to correct any deficiencies or inaccuracies present in an earlier filed oath or declaration.

(b) A supplemental oath or declaration meeting the requirements of § 1.63 must be filed: (1) When a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented; and (2) When an oath or declaration submitted in accordance with § 1.53(d) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new matter may be introduced into an application after its filing date even if a supplemental oath or declaration is filed (§ 1.53(b); § 1.118). In proper cases the oath or declaration here required may be made on information and belief by an applicant other than inventor.

30. Section 1.69 is amended by revising paragraph (b) to read as follows:

§ 1.69 Foreign language oaths and declarations.

(b) Unless the text of any oath or declaration in a language other than English is a form provided or approved by the Patent and Trademark Office, it must be accompanied by a verified English translation, except that in the case of an oath or declaration filed under § 1.63, the translation may be filed in the Office no later than two months from the date applicant is notified to file the translation.

31. Section 1.70 is amended by revising the title and paragraph (a) to read as follows:

§ 1.70 Oath or declaration under 35 U.S.C. 371(c)(4).

(a) When an applicant of an international application, if the inventor, desires to enter the national stage under 35 U.S.C. 371, he or she must file an oath or declaration in accordance with § 1.63.

32. Section 1.77 is amended by revising paragraphs (h) and (i) to read as follows:

§ 1.77 Arrangement of application elements.

(h) Abstract of the disclosure.

(i) Signed oath or declaration.

33. The center heading preceding § 1.97 and § 1.97 are revised to read as follows:
Information Disclosure Statement

§ 1.97 Filing of information disclosure statement.

(a) As a means of complying with the duty of disclosure set forth in § 1.56, applicants are encouraged to file an information disclosure statement at the time of filing the application or within the later of three months after the filing date of the application or two months after applicant receives the filing receipt. If filed separately, the disclosure statement should, in addition to the identification of the application, include the Group Art Unit to which the application is assigned as indicated on the filing receipt. The disclosure statement may either be separate from the specification or may be incorporated therein.

(b) A disclosure statement filed in accordance with paragraph (a) of this section shall not be construed as a representation that a search has been made or that no other material information as defined in § 1.56(a) exists.

34. Section 1.98 is amended by revising the title and paragraph (a) to read as follows:

§ 1.98 Content of information disclosure statement.

(a) Any disclosure statement filed under § 1.97 or § 1.99 shall include: (1) A listing of patents, publications or other information; and (2) A concise explanation of the relevance of each listed item. The disclosure statement shall be accompanied by a copy of each listed patent or publication or other item of information in written form or of at least the

1 of 6 DOCUMENTS

**ABBOTT LABORATORIES and CENTRAL GLASS COMPANY, LTD., Plaintiffs-
Appellants, v. BAXTER PHARMACEUTICAL PRODUCTS, INC. and BAXTER
HEALTHCARE CORP., Defendants-Appellees.**

02-1400

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

334 F.3d 1274; 2003 U.S. App. LEXIS 13507; 67 U.S.P.Q.2D (BNA) 1191

July 3, 2003, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Northern District of Illinois. Judge Ronald A. Guzman. *Abbott Labs. v. Baxter Pharm. Prods.*, 2002 U.S. Dist. LEXIS 26500 (N.D. Ill., Mar. 21, 2002).

DISPOSITION: VACATED and REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant owners challenged a decision from the United States District Court for the Northern District of Illinois, which granted summary judgment in favor of appellee applicants in a patent infringement case.

OVERVIEW: The owners' patent claimed compositions and methods of preventing the degradation of sevoflurane anesthetic by adding an effective amount of certain acid inhibitors. The applicants filed a request proposing to market generic sevoflurane. The product was composed of sevoflurane anesthetic with not more than a certain amount of water. The applicants contended that its request did not violate the owners' patent because it fell within the prior art. The owners later filed a claim for patent infringement. After the district court granted the applicants' motion for summary judgment, the owners sought review. In reversing, the court determined that the disputed claim term "effective amount" was construed in its ordinary and customary meaning. The owners' disclosure to the United States Patent and Trademark Office did not relinquish all water concentrations below a certain amount. Therefore, the district court incorrectly limited the term "effective

amount." Further, the specification did not require the district court to limit the claim to the preferred embodiments. Further, the owners should have been permitted to establish infringement under the doctrine of equivalents.

OUTCOME: The district court's decision was vacated. The case was remanded for further consideration of the infringement claim.

CORE TERMS: acid, sevoflurane, patent, inhibitor, effective, water, ppm, markush, specification, degradation, glass, invention, infringement, quantity, composition, anesthetic, patentee, disclosure, consisting, examiner, amount sufficient, fluoroether, embodiment, recited, summary judgment, amount of water, container, comprising, infringe, compound

LexisNexis (TM) HEADNOTES - Core Concepts:

Patent Law > Infringement > Claim Interpretation
Patent Law > Infringement > Summary Judgment
Patent Law > Jurisdiction & Review > Standards of Review

[HN1] Claim construction is a matter of law, which an appellate court reviews without deference. The appellate court reviews de novo all grants of summary judgment by a district court, drawing any reasonable inferences in favor of the nonmovant.

Patent Law > Infringement > Claim Interpretation

[HN2] Where a patentee does not deviate from the accustomed meaning of a disputed claim term, the term is construed in view of its ordinary and customary

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

meaning. Claim terms are afforded a "heavy presumption" that their ordinary and customary meanings apply.

Patent Law > Infringement > Claim Interpretation

[HN3] Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage. Only a clear disavowal of subject matter divests claims of broader scope. Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.

Patent Law > U.S. Patent & Trademark Office Prosecution Procedures > Filing Requirements

[HN4] According to the United States Trademark and Patent Office Rules, the filing of an information disclosure statement (IDS) shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to the patentability defined in 37 C.F.R. § 1.56(h) (2000). 37 C.F.R. § 1.97(h) (2000). While valid prior art may be created by the admissions of a party, these admissions are generally characterized by statements made during prosecution describing certain work as "prior art." Under certain circumstances, even an express representation that a reference cited in an IDS is prior art to pending claims is not sufficient to create prior art by admission. Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be material to prosecution of the pending claims. 37 C.F.R. § 1.56(a) (2000).

Patent Law > Infringement > Claim Interpretation

[HN5] An appellate court interprets patent claims in light of the specification, but this axiom does not mean that everything expressed in the specification must be read into all the claims. Claims are not necessarily and not usually limited in scope simply to the preferred embodiment. Thus, the specification does not require the claims to be limited to the preferred embodiments. The court declines to so limit the claims in this regard.

Patent Law > Specification & Claims > Alternative Limitations

[HN6] A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C. Therefore, if wherein R is a material selected from the group consisting of A, B, C

and D is a proper limitation then wherein R is A, B, C or D shall also be considered proper. A Markush group is a sort of homemade generic expression covering a group of two or more different materials (elements, radicals, compounds, etc.), mechanical elements, or process steps, any one of which would work in the combination claimed. Members of the Markush group are alternatively usable for the purposes of the invention. Moreover, a Markush group, incorporated in a claim, should be "closed," i.e. it must be characterized with the transition phrase "consisting of," rather than "comprising" or "including." Thus, members of the Markush group are used singly.

Patent Law > Specification & Claims > Alternative Limitations

[HN7] An indefinite article "a" or "an" in patent parlance carries the meaning of "one or more" in open-ended claims containing the transitional phrase "comprising." However, such an indefinite article used in conjunction with a Markush grouping does not receive such latitude because a proper Markush group is limited by the closed language term "consisting of." Therefore, although "a" without more generally could mean one or more in an open-ended patent claim, "a" with "consisting of" indicates only one member of a Markush group. If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim. Thus, without expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.

Patent Law > Infringement > Defenses > Invalidity

[HN8] Invalidity must be proven by clear and convincing evidence.

Patent Law > Infringement > Doctrine of Equivalents

[HN9] A patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the United States Patent and Trademark Office (PTO) by literal claims. Likewise, a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents.

COUNSEL: R. Mark McCareins, Winston & Strawn, of Chicago, Illinois, argued for plaintiffs-appellants. With him on the brief were Edward L. Foote, Raymond C. Perkins, and Peggy Balesteri. Of counsel were Blake T. Hannafan and James F. Herbison.

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

Constantine L. Trela, Jr., Sidley Austin Brown & Wood, of Chicago, Illinois, argued for defendants-appellees. With him on the brief were David T. Pritikin, William H. Baumgartner, Jr., Hugh A. Abrams, and Russell E. Cass. Of counsel on the brief was Thomas S. Borecki, Baxter Healthcare Corporation, of Deerfield, Illinois.

JUDGES: Before RADER, GAJARSA, and DYK, Circuit Judges.

OPINIONBY: RADER

OPINION: [*1275] RADER, Circuit Judge.

Plaintiffs-Appellants, Abbott Laboratories and Central Glass Company, Ltd. (collectively,

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **,
67 U.S.P.Q.2D (BNA) 1191

[*1276] Abbott), appeal the district court's grant of Defendants-Appellees Baxter Pharmaceutical Products, Inc. and Baxter Health Care Corp.'s (Baxter) motion for summary judgment of noninfringement. *Abbott Labs. v. Baxter Pharm. Prods.*, 2002 U.S. Dist. LEXIS 26500, No. 01-CV-1867, 2002 WL 449007 (N.D. Ill. Mar. 22, 2002). Because [**2] the district court erred in construing the asserted claims, this court vacates the district court's decision and remands for further adjudication.

I.

Abbott owns U.S. Patent No. 5,990,176 (the '176 patent), filed January 27, 1997, and issued November 23, 1999. The '176 patent claims compositions and methods of preventing the degradation of sevoflurane anesthetic by adding an effective amount of certain specific Lewis acid inhibitors. Abbott filed the '176 patent application after discovering that these Lewis acid inhibitors protected the shelf life of sevoflurane. Lewis acids attack sevoflurane at its ether and halogen linkages, thereby releasing hydrofluoric acid (HF) into the anesthetic. Because HF corrodes skin and mucous membranes, its presence in an anesthetic is harmful. HF also etches glass, and thus, exposes sevoflurane in glass vessels to additional Lewis acids and glass particles. Therefore, the '176 patent improved the storage and use of sevoflurane.

Baxter filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) proposing to market generic sevoflurane. Baxter's proposed product is a composition containing sevoflurane anesthetic with [**3] not more than 130 ppm water. Baxter also proposes to contain the composition in an aluminum vessel coated with an epoxyphenolic resin liner. In its application to the FDA, Baxter made a paragraph IV certification that its proposed generic sevoflurane product does not infringe

the '176 patent. Thereafter, Abbott filed this suit alleging infringement of the '176 patent. At issue are independent claims 1, 6, and 10 of the '176 patent (emphases added):

Claim 1.

An anesthetic composition comprising:

a quantity of sevoflurane; and

a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

Claim 6.

A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of:

providing a quantity of sevoflurane;

providing a Lewis acid inhibitor in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from [**4] the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol;

334 F.3d 1274, *; 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1277] combining said quantity of sevoflurane and the Lewis acid inhibitor in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.

Claim 10.

A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of:

providing a quantity of sevoflurane;

providing water in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane;

combining said quantity of sevoflurane and said water in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.

During prosecution of the '176 patent application, Abbott filed an Information Disclosure Statement (IDS) with the United States Patent and Trademark Office (USPTO). The IDS listed a reference indicating that at least one year before the filing date of the '176 patent, Abbott sold sevoflurane in glass bottles with a water content up to 131 ppm. Baxter seized upon this disclosure as a limit on the scope of the claims. Therefore, Baxter asserted [*5] that its generic sevoflurane with a water content of no more than 130 ppm falls within the prior art and does not infringe the '176 patent.

The district court agreed. Specifically, the district court construed the claim terms "amount effective" and "amount sufficient" of independent claims 1 and 6 to mean amounts above 131 ppm of water. Citing the '176 patent at column 4, lines 31-34, 45-47, and 56-58, the district court noted that the specification teaches that an effective stabilizing amount of Lewis acid inhibitor that "can be used" or "is believed to be" "about 0.150%w/w" (150ppm)." The district court acknowledged: "Nothing in the specifications [sic] inherently requires the amount of water to be 150 ppm or more." The district court said it

was "prepared to decline to limit its interpretation of the terms 'effective' or 'sufficient' amount to 150 ppm or greater but for Baxter's argument that the prosecution history of the '176 patent shows a prior sale which must limit the claims of the patent, lest it be invalid under 35 U.S.C. § 102(b)." *Abbott*, 2002 U.S. Dist. LEXIS 26500, 2002 WL 449007 at *4. Accordingly, the district court limited the claim terms "effective [*6] amount" and "amount sufficient" to water content above 131 ppm.

Based on this construction, the district court granted summary judgment of noninfringement to Baxter. The district court held that Baxter's product did not literally infringe the '176 claims because Baxter did not propose a sevoflurane product with more than 131 ppm water. Reasoning that disclosure to the USPTO of the prior sale of sevoflurane by Abbott surrendered the subject matter of the sale, the district court found no infringement under the doctrine of equivalents. Based on prosecution history estoppel, therefore, the district court declined to address infringement under the doctrine of equivalents. Abbott appealed to this court, which has exclusive jurisdiction. 28 U.S.C. § 1295(a)(1) (2000).

II.

[HN1] Claim construction is a matter of law, which this court reviews without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). This court reviews de novo all grants of summary judgment by a district court, drawing any reasonable inferences in favor of the nonmovant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986); [*7] *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1353 (Fed. Cir. 1998).

Effective Amount

The primary issue on appeal is the district court's construction of the claim term "effective amount." At the outset, this court notes that the term "effective amount" has a customary usage. Under this usage, the term would mean "the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." See *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002) (affirming the district court's construction of the claim term "effective

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1278] amount" to mean "a sufficient amount of the specified component to form an encapsulant having the specified properties under the specified conditions, if any").

Moreover, the '176 specification teaches that an effective amount of any given Lewis acid inhibitor will vary depending upon the conditions to which sevoflurane is subjected. The term "effective amount" is broadly described in the "Summary of the Invention" as an "effective stabilizing amount of Lewis Acid inhibitor" that "prevents the degradation of the fluoroether compound by a Lewis acid." '176 patent, [**8] col. 2, ll. 60-65. The specification teaches that degradation of fluoroether anesthetics, such as sevoflurane, vary depending upon the environment of the anesthetic. For example, the amount of Lewis acid inhibitor needed to prevent degradation of sevoflurane increases with increasing temperature. '176 patent, col. 8, ll. 18-20. Similarly, Type III glass, normally inert to sevoflurane, activates in some anhydrous, acidic environments. Activated glass exposes sevoflurane to Lewis acid reactive sites. '176 patent, col. 5, ll. 48-54. Examples 5-7 in the '176 patent inhibit degradation of sevoflurane by activated Type III glass by adding 400 ppm water.

Type I glass, chemically distinct from Type III glass, activates in the presence of 50 mg aluminum oxide, a known Lewis acid. Again, the specification addresses this degradation hazard by adding 260 ppm water. '176 patent, col. 5, ll. 55-col. 6, l. 16; Figure 1. The '176 patent thus explains that many different factors interact to dictate an "effective amount" of Lewis acid inhibitor to stabilize sevoflurane in a specific environment. [HN2] Because the patentee did not deviate from the accustomed meaning of the disputed claim term, the term "effective [**9] amount" is construed in view of its ordinary and customary meaning. *CCS Fitness, Inc. v.*

Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (stating that claim terms are afforded a "heavy presumption" that their ordinary and customary meanings apply). At a minimum, the '176 patent provides support for defining an "effective amount" of inhibitor to be the amount of Lewis acid inhibitor needed to stabilize sevoflurane housed in a particular glass vessel under a given set of environmental conditions. Thus, the specification supports the concept that the amount of Lewis acid inhibitor depends on many environmental considerations.

These principles also explain the relevance of the prior sale disclosed in the IDS. Particularly because the prior sale involved sevoflurane in a specific glass container with a water content of no more than 131 ppm, Abbott's disclosure to the USPTO did not disavow or relinquish all water concentrations below 131 ppm in other conditions. In the context of this invention, Abbott's disclosure did not expressly disavow claim scope. See *York Prods., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1575-76 (Fed. Cir. 1996) [**10] [HN3] ("Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage."). In *York*, for example, this court found no surrender of claim scope because the file history of the asserted patent did not contain "a single statement that the inventors conceded any coverage based on the [the prior art]," and the "mere invocation" of prior art does not necessitate limiting claim scope. *Id.* Indeed, this court recently reiterated the rule that only a clear disavowal of subject matter divests claims of broader scope. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313 (Fed. Cir. 2002). In *Teleflex*, this court stated: "We conclude that claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated

334 F.3d 1274, *; 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1279] an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* at 1324.

In this case, the district court incorrectly limited [*11] the term an "effective amount" of water to 131 ppm, despite the absence of a clear disavowal of water at lower amounts. Simply disclosing a previous sale of sevoflurane to the USPTO, without saying or doing anything more, does not disavow or relinquish all water concentrations below 131 ppm. As the patent itself discloses, the effective amount of Lewis acid inhibitor depends on the specific storage conditions of the sevoflurane. Moreover, mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art. [HN4] According to Patent Office rules, "the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to the patentability defined in § 1.56(b)." 37 C.F.R. § 1.97(h) (2000). While valid prior art may be created by the admissions of a party, these admissions are generally characterized by statements made during prosecution describing certain work as "prior art." See *In re Nomiya*, 509 F.2d 566, 571 n.5 (CCPA 1975); *In re Fout*, 675 F.2d 297, 300-01 (CCPA 1982). [**12] Under certain circumstances, even an express representation that a reference cited in an IDS is prior art to pending claims is not sufficient to create prior art by admission. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346 (Fed. Cir. 2003). Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be

material to prosecution of the pending claims. 37 C.F.R. § 1.56(a) (2000); see *A.R. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392 (Fed. Cir. 1986).

Although Abbott sold sevoflurane having water content levels of no more than 131 ppm several years before filing the '176 patent application, Abbott made no express representations about the relevance of these prior sales to the claims. Moreover, the examiner did not reject the claims over the disclosed prior sales of sevoflurane. The mere disclosure of potentially material art to the USPTO does not automatically limit the claimed invention. As noted, the examiner did not consider the sale relevant and the applicant did not distinguish the claims over the disclosed sale. Thus, this court concludes that [**13] the district court incorrectly relied on the IDS disclosure to limit the term "effective amount."

In reaching this conclusion, this court notes three instances in the specification where the applicant states an "effective amount" of water ranges from about 0.0150% w/w (150 ppm) to 0.14% w/w (saturation level). '176 patent, col. 4, ll. 32-36; 43-47; 55-58. Contrary to the district court's characterization, these references are not part of the "Summary of the Invention." Instead, these column 4 references fall within the "Detailed Description of the Invention." Thus, these references refer to the preferred embodiments of the invention. Because these references refer only to narrow preferred embodiments and not the invention as a whole, the specification passages do not support the limitation imported into the claims by the district court. The specification simply does not indicate that Abbott restricted its claims to the preferred embodiments. Instead, the specification refers to the water content in these preferred embodiments as amounts that "can be used" or "is believed to be" an appropriate Lewis acid inhibitor. These

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1280] descriptions in the specification are far from an express disavowal [**14] of other effective amounts.

[IIN5] This court interprets patent claims in light of the specification, but this axiom "does not mean that everything expressed in the specification must be read into all the claims." *Teleflex*, 299 F.3d at 1326. "Claims are not necessarily and not usually limited in scope simply to the preferred embodiment." *R.F. Del. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003). Thus, the specification does not require the claims to be limited to the preferred embodiments. This court declines to so limit the claims in this regard.

Neither does the prosecution history of the '176 patent limit the disputed claim terms. Early in the prosecution, the examiner cited *U.S. Patent No. 4,080,389* (issued to Moilliet) as anticipating the subject claims under 35 U.S.C. § 102. Moilliet discloses a fluoroether anesthetic composition containing water vapor. In response to this rejection, Abbott noted that Moilliet "merely indicates that water vapor may be present in the disclosed anesthetic composition . . . without specifying the amount of water present in the composition." At no time during this proceeding [**15] did Abbott reference the examples in its specification as the only specified water amounts that are "effective" to inhibit Lewis acids. In fact, Abbott never expressly represented that a particular concentration range of Lewis acid inhibitor was critical to distinguishing its claimed invention over Moilliet. Rather, Abbott overcame Moilliet by simply differentiating the trace amounts of water vapor taught in that reference from the claimed amount of water effective as a Lewis acid inhibitor in sevoflurane. At best, Abbott disavowed trace amounts of water as being effective in stabilizing sevoflurane. Thus, this prosecution history does not

support limits on the terms "effective amount" or "amount sufficient."

Markush Grouping of Lewis Acids

Asserted claims 1 and 6 recite a list of Lewis acid inhibitors presented in the form of a Markush group. Citing *KCI Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000), Abbott argues that the recitation of "a" Lewis acid inhibitor in claims 1 and 6 is understood to mean that "more than one inhibitor would still fall within the claim boundaries." In arguing this construction, Abbott does not account for [**16] the Markush groups in claims 1 and 6.

[HN6] A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C. Therefore, "if 'wherein R is a material selected from the group consisting of A, B, C and D' is a proper limitation then 'wherein R is A, B, C or D' shall also be considered proper." *In re Harnisch*, 631 F.2d 716, 724 (CCPA 1980) (containing an Appendix describing Patent Office practice); see Manual of Patent Examining Procedure (MPEP) § 2173.05(H) (8th ed. 2001); see also Robert C. Faber, Landis on Mechanics of Patent Claim Drafting, § 50, 5A, VI-5-6 (4th ed. 2002) ("A Markush group is a sort of homemade generic expression covering a group of two or more different materials (elements, radicals, compounds, etc.), mechanical elements, or process steps, any one of which would work in the combination claimed."). It is well known that "members of the Markush group are . . . alternatively usable for the purposes of the invention." *In re Driscoll*, 562 F.2d 1245, 1249 (CCPA, 1977). Moreover, "[a] Markush group, incorporated in [**17] a claim, should be 'closed,' i.e. it must be characterized with the transition phrase 'consisting of,' rather than 'comprising' or 'including.'"

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1281] Stephen A. Becker, Patent Applications Handbook § 2:17 (9th ed. 2000). Thus, "members of the Markush group are used singly." See Meeting Held to Promote Uniform Practice In Chemical Divisions, 28 J. Pat. & Trademark Off. Soc'y 849, 852 (1946) (listing practices approved by the primary examiners of the USPTO's chemical group).

In *KJC Corp.*, this court stated that [HN7] "an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *KCI Corp.*, 223 F.3d at 1356. However, such an indefinite article used in conjunction with a Markush grouping does not receive such latitude because a proper Markush group is limited by the closed language term "consisting of." See *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986) (confirming that the phrase "consisting of" appearing in a clause of a claim specifically limits only the element set forth in that clause). Therefore, although [**18] "a" without more generally could mean one or more in an open-ended patent claim, "a" with "consisting of" in this case indicates only one member of a Markush group. See *KCI Corp.*, 223 F.3d at 1356. If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim. See Meeting Held to Promote Uniform Practice In Chemical Divisions, supra, at 852 (citing examples of qualifying language such as: "and mixtures thereof" and "at least one member of the group"). Thus, without expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.

Abbott's claims do not have such qualifying language. Because the claims do not clearly embrace

more than one member of the Markush group, only one Lewis acid inhibitor falls within the claim scope. Thus, the plain meaning of asserted claims 1 and 6 limits them to a single Lewis acid inhibitor selected from the recited Markush group, and present in an amount effective to prevent degradation of sevoflurane by Lewis acids.

The [**19] file history of the '176 patent supports this analysis. Abbott amended the '176 patent claims during prosecution. Independent claim 1, as initially filed, recited "a fluoroether compound having an alpha fluoroether moiety having added thereto an effective amount of a Lewis acid inhibitor." Independent claim 6, as originally filed, recited "adding to the fluoroether compound an effective stabilizing amount of a Lewis acid inhibitor to prevent the degradation of the fluoroether compound by the Lewis acid." After amendment, claims 1 and 6 recite a specific inhalant anesthetic, sevoflurane, and specific Lewis acids inhibitors, '176 patent, col. 11, ll. 22-29. In an Interview Summary, the examiner stated that he reached agreement with applicants "to narrow the claims to include a specific inhalant anesthetic and specific Lewis acid inhibitors in order to avoid 112 issues." The examiner's reasons for allowance made the same observations.

Thus, the patent applicant added the Markush group reciting specific Lewis acid inhibitors to comply with 35 U.S.C. § 112 and gain allowance. In doing so, Abbott disclaimed any coverage for Lewis acid inhibitors other than the six [**20] listed members of the Markush groups in issued claims 1 and 6. Consequently, the file history shows that the applicant expressly defined the claim term "Lewis acid inhibitor" as a member of the recited Markush group. Thus, claims 1 and 6 embrace a Lewis acid inhibitor selected from those inhibitors recited in the Markush group.

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1282] III.

This court need not construe the claims of the '176 patent as requiring more than 131 ppm of water to preserve their validity under 35 U.S.C. § 102(b) in view of Abbott's prior sale of sevoflurane. In the first place, the district court expressly declined to determine the validity of the '176 patent claims. The district judge noted that the parties did not raise the issue of validity and also observed that the "clear and convincing evidence" required to invalidate a patent has not yet been shown here." *Abbott*, 2002 U.S. Dist. LEXIS 26500, 2002 WL 449007 at *6. Despite this observation, the district court concluded that "the only way to maintain the validity of the '176 patent, then, would be to interpret the terms 'sufficient' or 'effective' amount as requiring at least 131 ppm of water." In effect, the district court reached out to make [*21] a validity determination, despite the lack of invalidating evidence.

It is sometimes difficult to balance a patentee's broad claim reading against an assertion that the claims at some indefinite breadth may be invalid. See *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001). In this case, however, the district court did not have evidence that Abbott's sale of sevoflurane constituted prior art to the claimed invention. The record did not show whether the previously sold sevoflurane contained an amount of water capable of effectively inhibiting Lewis acids under those unique storage conditions. The record does contain Abbott's assertion that the amount of water in the previously sold sevoflurane compositions was ineffective for preventing degradation of sevoflurane in glass bottles. Abbott contends that this problem provided the impetus for its studies that ultimately lead to the '176 patent. As noted, Baxter does not adequately address whether the prior sale is truly material prior art to the claimed invention. Rather, Baxter incorrectly assumes that disclosure of a

reference to the USPTO is an admission that the reference is material prior [*22] art.

The district court properly noted that [HN8] invalidity must be proven by clear and convincing evidence. *Tate Access Floors, Inc. v. Interface Architectural Res.*, 279 F.3d 1357, 1367 (Fed. Cir. 2002). Without such evidence, and without the issue of validity properly presented for the record, the district court erred by giving the claim term "effective amount" a narrow reading to preserve its validity. On remand, if the issue of validity is properly presented, the court will have the opportunity to determine whether this prior sale affects the validity of the claims.

IV.

The district court granted summary judgment of noninfringement based on its claim construction restricting water as a Lewis acid inhibitor only when present in sevoflurane at an amount greater than 131 ppm. The district court determined that Baxter's proposed sevofluorane composition contains not more than 130 ppm, and therefore, does not literally infringe the '176 patent. Because the district court's construction is flawed, this court remands for further consideration of literal infringement in view of the claim construction discussed herein.

Abbott argues that Baxter's sevoflurane composition [*23] having less than 131 ppm water in a vessel possessing an epoxyphenolic resin liner literally infringes the '176 claims under its proffered construction. Abbott notes that Baxter's combination of two Lewis acid inhibitors, even if each is individually present at an ineffective amount, results in an amount of Lewis acid inhibitor capable of effectively inhibiting sevoflurane degradation by Lewis acids. This combination, according to Abbott, satisfies the claim element of "a Lewis acid

334 F.3d 1274, *, 2003 U.S. App. LEXIS 13507, **;
67 U.S.P.Q.2D (BNA) 1191

[*1283] inhibitor" and therefore, it was error for the district court to decide infringement on summary judgment when this issue of material fact was still in dispute. Abbott does not properly consider the constraints placed on claims 1 and 6 by the introduction of the Markush group during prosecution, as discussed above. To prove literal infringement of these claims on remand, Abbott must show a species selected from the members of the recited Markush group is present in Baxter's sevoflurane composition in an amount effective to function as a Lewis acid inhibitor.

Despite a listing of various suitable container materials - glass, plastic, and steel - in column 5, the district court "found no mention in the '176 [*24] patent that the type of container would make a difference" in the amount of Lewis acid inhibitor required in a given packaging. To the contrary, the specification clarifies that, at least with respect to glass containers, the amount of Lewis acid inhibitor varies depending upon the type of glass and other characteristics and conditions of the container. Moreover, the specification need not teach that which is already known to artisans of ordinary skill. Therefore, on remand, the court will have the opportunity to develop a record on this point as well.

Abbott also contends the district court erred by barring it from asserting infringement under the doctrine of equivalents. The district court determined that the doctrine of equivalents was not available to Abbott "because of the prior art sale," citing *Wilson Sporting Goods Co. v. David Geoffrey & Associates*, 904 F.2d 677, 684 (Fed. Cir. 1990) (stating [HN9] "a patentee

should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims"). Likewise, this court has opined "a patentee cannot narrowly claim an invention to avoid prosecution scrutiny [*25] by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents." *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc). It may be argued that requiring a patentee to claim subject matter that the patent drafter reasonably could have anticipated and described during the application process serves to "enhance[] the notice function of claims." *Id.* at 1056-57. The district court declined to consider the applicability of infringement by equivalents in view of *Festo*, which was under consideration by the Supreme Court at the time the district court's decision was rendered. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002). On remand, Abbott will have the opportunity to establish infringement by equivalents in view of this court's claim construction. The effect of the decisions in *Wilson Sporting Goods*, *Johnson & Johnston*, and *Festo* on infringement of the '176 patent via equivalents should be evaluated by the district court. In sum, this [*26] court vacates the district court's decision, and remands for further consideration of infringement consistent with this opinion.

COSTS

Each party shall bear its own costs.

VACATED and REMANDED